

FROM :
MAY 03 2001 14:03 212 382 2124

PHONE NO. :
STEINBERG & KASKIN, P.C.

Jul. 21 2000 04:05PM P3
51109 R.JUL2100

860.1901

UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor : Milton Hodosh
Serial No. : 09/072,504
Filed : May 4, 1998
For : METHOD AND COMPOSITION FOR
PREVENTING TOOTH
HYPERSENSITIVITY WHEN USING
PASSEVE BLEACHING AGENTS
Art Unit : 1614

#18
SUBJ
5/901

AFFIDAVIT OF ALEX HODOSH
UNDER 37 C.F.R. 1.608(b)

I, Alex Hodosh, declare as follows:

1. I am a doctor of dentistry with over ten years experience in the dentistry field and have extensive experience conducting dental bleaching treatments and other dental treatments which may cause hypersensitivity to the patient.

2. On a date prior to May 30, 1997 I witnessed a test conducted by Milton Hodosh. My signature bearing witness to the test appears at the bottom of Milton Hodosh's research notes, copy of which are attached hereto as Exhibit 1.

FROM :
MAY. 03'2001 14:04 212 382 2:24

PHONE NO. :
STEINBERG & RASKIN, P.C.

Jul. 21 2000 04:06PM P4
#1159 P.003/003

3. In the test Milton Hodosh combined KNO₃ with a bleaching compound available under the brand name "Karisma". The object of the test was to obtain a dental bleaching composition which prevented hypersensitivity.

4. The bleaching compound "Karisma" is manufactured by Confidential-Products Co. located at 325 S. Pierce Ave., Colorado Tech Center, Louisville, CO, 80027-3017. On information and belief "Karisma" contains carbamide peroxide as the active bleaching agent and a sticky matrix material that includes carboxypolyethylene.

5. The dental composition was administered to at least nine patients utilizing a dental tray which was adapted to hold the dental composition adjacent a person's tooth surfaces.

6. In each of the nine patients the dental bleaching composition effectively whitened patient's teeth and no hypersensitivity was reported.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

5-3-01
Date



Alex Hodosh

Research Notes

Combined 5%, 10%, 15% saturated KNO_3 with Karsin (Carbamide Peroxide in a glycerine base) & C.V.S. Oral cleansing anticipated (also 10% Carbamide Peroxide in a glycerine vehicle with citric acid, Propylene Glycol, flavor, sodium stearate, & water). Karsin received from Dr. Brahma Sharma of Confine Dental Products, Inc. [REDACTED]

Object - use in combination with peroxide yielding bleaching agents to prevent hypersensitivity seen with high frequencies when passive bleaching products are used especially in traps. [REDACTED]

Study for [REDACTED]
- Custom Traps made from impressions
models using the Amiswax - 5% KNO_3
added to Karsin in 9 subjects
10% added to GBS in 16 subjects following
the addition of 10 more % Carbamide
Peroxide to the CPS product - to see
if could obtain more bleaching capability
of increased hypersensitivity produced from
20% Carbamide Peroxide.

In all cases no hypersensitivity resulted - the 13% & 20% traps (without potassium nitrate) were unnecessary.

[REDACTED] values - [REDACTED]

Melton

Sylvia Blasor

Janet Gibbs

Randy Gibbs

Judith Litchman

Barry Cohen

Fred Blasor

Belle David

Estelle Hodosh

Jan Gilbane

✓ above pts given Karoma $\pm .57 \text{ KNO}_3$
added - no sensitivity encountered

Patients given CVS oral cleansing Antiseptic

Barry Cohen

Jan Gilbane

Barbara Shulkin

Jackie Hodosh

Judith Litchman

Mildred Connors

W. Collomore